UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI INC, and KBI-E INC. Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs	Civil Action No. 3: 11-cv-00760-JAP-TJB

DECLARATION OF ROBERT P. NAVARRO, PHARM. D.

I, Robert P. Navarro, declare as follows:

I. QUALIFICATIONS AND BACKGROUND

1. I am currently a Clinical Professor in the Department of Pharmaceutical Outcomes & Policy at the University of Florida College of Pharmacy. In addition, I am President of Navarro Pharma, LLC, a managed care pharmacy consultancy serving the managed care and pharmaceutical industries.

2. I am an expert on managed care prescription drug programs. For over 30 years, I have been personally involved in developing and managing prescription drug programs for managed care organizations on behalf of employer group customers, and I have served on numerous Pharmacy & Therapeutics Committees for health plans and pharmacy benefit managers (PBMs). I also have consulted with health plans, PBMs, and the legal profession on managed care prescription drug programs. My curriculum vitae is attached as Exhibit A, which includes a listing of the proceedings in which I have testified as an expert or have presented an expert report.

3. I was educated and trained as a clinical pharmacist and was awarded a Doctor of Pharmacy degree from the University of Minnesota College of Pharmacy in 1977. I previously was awarded BS (biology) and BS (pharmacy) degrees from St. John's University (Minnesota) and the University of Minnesota College of Pharmacy, respectively. I was licensed to practice pharmacy in the State of Minnesota, but voluntarily surrendered my license in 1995, as it was unnecessary in the non-dispensing, pharmacy management positions that I held at health plans and PBMs.

4. My professional career has included the following positions/roles:

- Community pharmacist and medical center pharmacy part-owner;
- Long term care consultant pharmacist;
- Hospital clinical pharmacist;
- Medical school pharmacology instructor;
- Managed care pharmacy director in two health plans;
- Associate Vice President of Provider Services in a health plan;
- Co-developer of two PBMs;
- Vice President of Pharmacy & Therapeutics in a PBM;
- Author and lecturer on managed care issues;
- Pharmaceutical industry consultant on managed care pharmacy issues; and
- Clinical Professor, Department of Pharmaceutical Outcomes & Policy, at the University of Florida College of Pharmacy, teaching managed care courses in the graduate program, the PharmD program, other graduate course and seminar development, and various committee and administrative responsibilities.

5. In 1982, I joined United HealthCare (UHC), now one of the largest national health insurance companies, to help build a pharmacy department and develop a program to offer pharmacy benefits. In 1983, I became Pharmacy Director at UHC, and at one of UHC's largest health plan clients, Physicians Health Plan of Minnesota (PHPM), which is now called Medical, then a million member health plan. My first involvement with managing pharmacy benefits came in 1983-84, when I wrote the first drug formulary for PHPM, which subsequently became the basis for the UHC and Diversified Pharmaceutical Services formularies. In that same period, I designed and implemented policies and procedures to enforce the formulary, and helped develop the managed care industry's first pharmaceutical rebate contract in 1984.

6. In 1988, I became Director, and in 1990, Associate Vice President of Provider Services, at Health Net, then a one-million member health plan in California, and developed and managed the prescription drug benefit. My responsibilities included developing Health Net's first comprehensive prescription drug benefit, developing and contracting with a pharmacy network, and developing and marketing customized prescription drug benefit programs.

7. From January 1993 through mid-1996, I began consulting with pharmaceutical companies, initially through a consultancy known as Emron, and then through my own company, Navarro Pharma LLC. During this period, I assisted the National Association of Chain Drug Stores (NACDS) in developing its own PBM, which was later purchased by American Drug Stores as part of its PBM, Rx America.

8. In 1996, I became Vice President of Pharmacy & Therapeutics at Express Scripts, Inc. ("ESI"), now the country's largest PBM, and was responsible for the development of pharmacy point-of-service claims adjudication system edits and clinical pharmacy programs.

9. In 1999, I left ESI to return to my independent health care consultancy, Navarro Pharma LLC, which I continue today in addition to my University of Florida position.

10. In 2011, I joined the University of Florida College of Pharmacy faculty as Clinical Professor in the Department of Pharmaceutical Outcomes & Policy, and I teach managed care-related classes in the graduate and Doctor of Pharmacy programs.

11. In 2012, I became involved in the management of the pharmacy benefit of GatorCare, a self-funded health plan of the Shands Medical Center-University of Florida. In this capacity, I was involved in writing the PBM request for proposal (RPF), reviewing the PBM

RFP submissions, selecting the PBM, and continue to be involved in monitoring the performance of the pharmacy benefit and making recommendations for benefit change.

12. I served as a voting member of managed care Pharmacy & Therapeutics (P&T) Committees for 13 years at UHC, PHPM, Diversified Pharmaceutical Services, Health Net, and ESI. Since 1996, through my consultancy practice, I also have consulted with the pharmaceutical industry on evaluating Phase III and Phase IV clinical trials, developing new drug value propositions, and pricing and contracting strategies. I have also conducted numerous new drug market research projects using heath plan and PBM medical and pharmacy directors, and have conducted payer customer advisory boards.

13. I have been on the Journal of Managed Care Pharmacy (JMCP) Editorial Advisory Board since 2006, and in 2012, served as interim editor of the JMCP. I also am editor of both editions of the textbook Managed Care Pharmacy Practice (Aspen Publications, 1999; Jones & Bartlett, 2009), and have recently agreed with this publisher to begin work on the third edition of this textbook. I have also been lead author of three chapters about prescription drug benefits in Institutional Pharmacy Practice (American Society of Health-System Pharmacists, 2005) and Essentials of Managed Care, 4th, 5th, and 6th editions (Aspen publications, 1999; Jones & Bartlett Publishers 2007, 2012).

14. I was a co-founder and the first President of the Academy of Managed Care Pharmacy ("AMCP") and the Foundation for Managed Care Pharmacy ("FMCP"), which were formed in 1989. The AMCP now has over 7,000 members and is the only professional organization representing pharmacists practicing in managed care organizations, the pharmaceutical industry, and related organizations.

15. My areas of expertise — based on my training, experience, and research — include the following:

- Development and operation of managed prescription drug programs;
- Development of employer group and member prescription benefit contracts and pharmacy benefit design;
- Development of a pharmacy provider network, including pharmacy negotiations and development of a Participating Pharmacy Provider Manual;
- Evaluation of health plans' and PBMs' pharmacy benefit program financial and clinical performance;
- Development, management, and enforcement of drug formularies by health plans and PBMs;
- Review and evaluation of drugs by health plans, PBMs, and their P&T Committees, including the use of clinical, economic, and humanistic data in drug formulary decisions;
- Development of new drug value propositions, new drug marketing, contracting, and pricing strategies on behalf of pharmaceutical manufacturers; and
- Writing and lecturing on managed care prescription drug benefit programs.

II. SUMMARY OF ANALYSIS

16. I have been retained in this matter by plaintiffs AstraZeneca AB, Aktiebolaget Hassle, KBI-E Inc., KBI Inc. and AstraZeneca LP (collectively, "AstraZeneca") to: a) provide a description of the mechanisms used by health plans, health insurance companies, and pharmacy benefit managers (PBMs) to control the cost of prescription drug benefits; b) analyze and provide an opinion on the impact of "esomeprazole strontium delayed-release capsules"[1] by Hanmi and its U.S. marketing partner Amneal ("the Hanmi product") on the immediate and long-term coverage and use of Nexium® in managed care prescription drug programs, if esomeprazole

[1] This product has also been identified in some documents as esomeprazole strontium.

strontium delayed-release capsules is allowed to enter and remain on the market; and c) the likely confusion that would result from entry of the Hanmi product into the market.

III. MANAGED CARE FUNDAMENTAL CONCEPTS

17. The concept of managed care began in the early 20th century in isolated areas of the U. S., including northern Minnesota, where iron mines provides group health coverage for mine workers, and Henry Kaiser provided health coverage for shipbuilders in southern California. A Minnesota physician, Paul Ellwood, MD, a healthcare policy consultant, is credited for creating the term "health maintenance organization" (HMO) in the 1970s. Dr. Ellwood's vision for managed care was for an affordable group healthcare coverage program that provided and promoted preventive care, healthy lifestyle resources, and used specific management strategies to control costs and use of covered healthcare products and services. The HMO Act signed by President Nixon in 1973 provided substantial funding for developing HMOs that conformed to specific organizational and operational requirements (so called "federally funded HMOs").

18. Managed health care is a pre-paid, subscription health care financing and delivery system with defined contributions and defined benefits (inclusions and exclusions), along with financial incentives and penalties designed to influence physicians, hospitals, other providers, and patients to follow policies and procedures which promote the cost-effective use of resources. The primary healthcare benefits offered by health plans and health insurance companies are physician (outpatient physician, diagnostic, devices, and other services), hospital (inpatient services), and outpatient prescription drug benefits. Some plans and insurers offer dental and other optional benefits. PBMs only offer prescription drug benefits. Physician and hospital benefits, together, are referred to as "Medical Benefits", that are distinct from Pharmacy Benefits

(often terms Prescription Drug Benefits).

19. In this report, I use the term "Managed Care Organizations" to refer to health plans, health insurance companies, and PBMs using the managed care concepts discussed above. Health plans and health insurance companies provide medical, hospital, device, pharmacy benefits, and possibly other related health benefits. In this report the term "Health Plans" includes health insurance companies. The term "PBM" refers to entities that primarily offer prescription drug benefits, and not medical or hospital benefits. The following three strategies are key characteristics of Managed Care Organizations.

20. First, all individual and entities that participate in a managed care system (e.g., medical groups, hospitals, pharmacies, employer groups, members, and others) share in the financial risk of the cost of the program (often termed a "shared risk" arrangement). Risk-sharing is designed to incentive all participants to provide and use resources wisely, according to the provisions of the purchased benefit. For example, providers (e.g., physicians, pharmacies, hospitals) share in the financial risk by accepting discounted reimbursement in exchange for the opportunity to participate with a Managed Care Organization. Members (e.g., patients) are individuals eligible for coverage. Members must often pay a cost share (e.g., copayment, coinsurance) when they access or obtain covered benefits.

21. Second, benefit contracts between benefit purchasers and Health Plans PBMs (contracts are often termed the "Evidence of Coverage" or Certificate of Coverage") define the benefits that are included in insurance coverage, define the excluded benefits, and also describe the process that must be followed to obtain covered benefits (for example, covered benefits may be limited only to services provided by contracted providers). Thus, only specifically defined

benefits are eligible for coverage under the insurance plan purchased by a Plan Sponsor. Benefits obtained by a patient outside of those specified are not eligible for coverage under the Certificate of Coverage may require the patient pay to cash outside of insurance coverage.

22. Third, Managed Care Organizations control the supply (identity) of the products and services eligible for reimbursement by providers, and also the demand (utilization rate) of benefits eligible for coverage. For example, Health Plans and PBMs specifically determine what drugs (including dosage forms and strengths) are eligible for coverage as well as the frequency and amount of a covered drug that may be obtained by Members within a specific time period. These control mechanisms are described further below.

23. Managed Care Organizations design a program of covered benefits specifically for each purchaser through a negotiated process to match the cost and benefit richness desired. The process of setting a price on a specific benefit plan is termed "Underwriting". The purchaser of health insurance benefits is often termed "Plan Sponsor", and may be an employer group, a state Medicaid program, an individual person, or a health and welfare benefit trust, or other entity). I shall use the term Plan Sponsor when referring to a purchaser of a medical or pharmacy benefit.

24. I use the term "Member" to refer to individual persons who obtain covered benefits. "Members" include Subscribers (who are the employees in employer-based programs), covered dependents, and Recipients or Beneficiaries who are participants in Medicaid or Medicare programs).

25. PBMs offer comprehensive and customized prescription drug programs for Health Plans as well as self-funded employer groups that may have "carved-out" the pharmacy benefit from a Health Plan. In this carve-out situation, employer groups contract directly with a PBM for

pharmacy benefits, and contract separately with a Health Plan for medical benefits. Health Plans often purchase specific services from PBMs, including a pharmacy distribution network, claims adjudication, and take advantage of discounts or rebates negotiated by PBMs from pharmaceutical manufacturers. Health Plans may purchase other PBM services, including clinical and prescription adherence programs (including support of Medicare-specific quality programs), formulary management services, and customized drug utilization reporting, among other services. PBMs generally do not accept fiduciary risk on behalf of their Health Plan and self-insured employer group customers, but offer performance guarantees based upon achieving the cost and quality outcomes specified in customer contracts with PBMs.

IV. PHARMACY BENEFIT PROGRAM MANAGEMENT STRATEGIES

26. Health Plans, insurers, and PBMs use various management strategies to control the cost and utilization rate of covered prescriptions drugs (and non-prescription drugs if covered). These strategies are applied in a customized approach to satisfy the specific cost and quality outcomes benefits that have are purchased for each Plan Sponsor. The primary management strategies are described below.

A. Cost and Quality Management Strategies

27. **Evidence of Coverage.** The contract between the plan, insurer, or PBM and the Plan Sponsor (also may be called the Certificate of Coverage) defines the covered and excluded benefits, as well as the requirements to obtain covered benefits (e.g., the Member must obtain prescriptions only from contracted network pharmacies). The benefits may be summarized in a document for Members written in lay terminology, perhaps in different languages. The term "Benefit Design" is often used to refer to the benefits and access rules for a specific benefit program.

28. **Member Cost Share.** Members must often pay a portion of the cost of the covered benefits they use, such as a copayment or coinsurance for each prescription they obtain. The cost share accomplishes two objectives. First, program costs are reduced for Plan Sponsors (prescription cost share amounts for brand drugs are usually 25% - 50% of the cost of the prescription), and the cost share reduces moral hazard.

29. **Claims Adjudication.** Over 98% of managed care outpatient prescription drug claims are adjudicated (priced and confirmed as eligible for coverage) in a real-time, online pharmacy point-of-service (POS) claims adjudication system. The POS claims adjudication systems of all plans, insurers, and PBMs, and retail pharmacies use identical claims processing data standards. POS claims processing systems allow accurate enforcement of customized Benefit Designs of Plan Sponsors, including enforcement of Drug Formulary coverage rules.

30. **Prescription Adjudication Edits.** The pharmacy POS systems allows enforcement of Drug Formulary coverage limitations and restrictions. These limitations and restrictions, such as "generic first" step edits and prior authorization are customized for each Plan Sponsor, when necessary, and are important Drug Formulary enforcement mechanisms.

31. **Step Edits.** When lower cost generic alternatives exist for brand drugs (even with a different active molecule but in the same therapeutic class), Managed Care Organizations may impose an automated step edit that requires a Member to have tried a generic product in a specific therapeutic class (e.g., PPI) before the plan or PBM will reimburse for a brand drug within the same therapeutic class. An example of a PPI-class step edit is the requirement for a Member to receive a generic Formulary PPI before a brand PPI is eligible for reimbursement (termed a "generic first" step edit). The automatic step edits are enforced with the POS claims adjudication

system. If a pharmacist enters the drug identification code for a brand PPI that is subject to a generic first step edit into the POS system, the POS system automatically checks the Members drug use claim history for evidence that a generic PPI has been used. If the system finds a previous claim for a generic PPI, the system automatically approves the step edit, and the pharmacist may dispense and be reimbursed for the brand PPI. If the adjudication system does not find evidence of previous generic PPI use, the pharmacist receives an error message identifying the brand drug as ineligible for reimbursement.

32. **Prior Authorization (PA).** Brand drugs may be subject to a prior authorization (termed "precertification" by some plans), which requires the prescribing physician to provide specific information about the medical condition or intended medical use for a brand drug subject to a PA. Reasons for PA prescribing and dispensing restrictions include high cost, safety concerns, abuse or misuse potential, off-label use concerns, special handling, limited availability, or other reasons.

33. **Quantity and/or Duration Limits.** Limits on quantity or duration of use may be placed on drugs with a potential for overuse, abuse, excessive dose or duration of use. For example, drugs that may have an abuse potential, such as a sedative-hypnotic, may be limited to a three month duration for each original prescription.

34. **Pharmacy Distribution Network.** Health Plans and PBMs customize pharmacy distribution channels for each Plan Sponsor. The three primary prescription distribution channels include retail community, mail service, and specialty pharmacy (e.g., injectable and high-risk

drugs).[2] Pharmacies participating in a pharmacy-provider network agree by contract to accept discounted reimbursement. Health Plans and PBMs construct customized pharmacy-distribution channels to accommodate specific Plan Sponsor cost and quality objectives.

35. **Drug Formulary.** A Formulary (or Preferred Drug List) is a dynamic document that lists drugs eligible for reimbursement. Formularies are often categorized as "open" or "closed", a term that reflects how tightly they are controlled. Formulary drugs are often organized by human organ system and/or therapeutic class, and sub-categorized in Tiers most commonly by one of four general types of drugs: Tier 1, for lowest cost drugs, often generic drugs; Tier 2, for preferred brand drugs; Tier 3 for non-preferred brand drugs; and, Tier 4 for specialty drugs[3]. Each Tier is associated with a specific Member cost-share amounts (such as a co-payment or coinsurance) designed to incentivize use of the least expensive drug that is clinically acceptable. For example, the lowest cost share is assigned to a Tier 1 generic drug, and higher cost shares are generally assigned to successively higher Tiers. Formularies are updated from time to time, as newly available drugs (and other drugs may be repositioned or removed). Formulary drug decisions are generally made by a group of physicians and pharmacies termed the Pharmacy & Therapeutics Committee (P & T Committees). Drug Formularies are highly individualized to meet the specific business and Member type needs.

36. Open Formularies often contain more drugs than closed Formularies. Open Formularies often provide coverage for most drugs, and exclude few drugs. Open Formularies use a Tier structure with cost-share incentives, step edits, and prior authorizations to enforce

[2] Approximately 75% of outpatient drugs are dispensed through retail community pharmacies (pharmacy chains, independent, and other pharmacies), 20% of prescriptions are dispensed through mail services pharmacies, and, 5% of prescriptions are dispensed through specialty pharmacies.

[3] Specialty drugs often include injectable drugs, biological, very expensive drugs, and drugs that may require

Formulary conformance. Open Formularies are common in most Blue Cross Blue Shield plans, many large insurers (e.g., United HealthCare, Aetna, Humana), and many other Health Plans and PBMs.

37. Closed Formularies often contain fewer drugs than Open Formularies, and are much more highly controlled. Closed Formularies, common in integrated, closed model Health Plans (e.g., Kaiser Permanente, and others) develop limited Formularies, and often exclude coverage for brand drugs with generic alternatives (e.g., having the same active ingredient).

38. Each Health Plan and PBM generally has its own P & T Committee to make drug formulary decisions specific for each Plan Sponsor group type. Drugs included in Drug Formularies are subject to the reimbursement limitations and restrictions discussed above.

39. An example of a typical Formulary Tier structure and possible cost share levels is illustrated below:

Formulary Tiers	Drugs Included in Tier and Relative Cost Index	Member Payment
Tier I - Generic	• *lansoprazole* • *omeprazole* • *omeprazole/bicarbonate* • *pantoprazole*	$10.00
Tier II - Preferred Brand	• Nexium® • Dexilant®	$25.00
Tier III - Non-Preferred Brand	• Aciphex®* • Prevacid®* • Prilosec®* • Protonix®* • Zegerid®*	$50.00

*-Signifies generic first-step edit (generic must be used before brand).

40. **Pharmaceutical Manufacturer Rebates.** Health Plans, insurers, and PBMs may

specialty handling. Specialty drugs are usually managed and dispensed by specialty pharmacies.

contract with pharmaceutical manufacturers to obtain a discount or rebate on specific brand name drugs that may be repositioned in a preferred position on Drug Formularies (e.g., Tier 2 rather than Tier 3). Drugs in a preferred position (or lower Drug Formulary Tier) are considered less expensive, and have a lower cost share compared to drugs in higher Drug Formulary Tiers. This improved Formulary position generally increases prescription utilization and drug sales.

41. **Clinical and Quality Programs.** Health Plans and PBMs offer a variety of clinical and quality improvement programs to improve the clinical performance or reduce safety risks of covered drug products. Examples of such programs include drug utilization review (to identify drug misuse or abuse), drug adherence programs (to improve Member drug compliance), or quality measurement programs (such as NCQA HEDIS measures that offer report on Health Plan or PBM performance).

42. These primary pharmacy benefit management or cost management strategies commonly result in Health Plans and PBMs achieving over 95% conformance with their drug formulary, depending upon the Drug Formulary type. It is important to note that Health Plan or PBM strategies control or influence the reimbursement of over 90% of all outpatient prescriptions dispensed in the US.

B. Practical Application of Cost Management Strategies

43. In practice, the process of prescribing and dispensing covered drug products in a managed care system is familiar.

44. First, a Health Plan Member consults a physician participating with the Health Plan. After considering the clinical condition of the Member, the physician consults the Health Plan's Drug Formulary to select a reimbursable drug that will satisfy the Member's medical needs.

Physicians generally prescribe the drug with the lowest Member cost share that is medically acceptable (Tier 1 if possible; Tier 2 if necessary; Tier 3 as last choice). Additional prescribing limitations and edits present further deterrents to higher cost drugs being prescribed.

45. Then, the Member takes the prescription to a participating network pharmacy to be filled. The pharmacist uses the POS claims adjudication system to determine Member eligibility and drug reimbursement status. Pharmacists are informed of the Drug Formulary Tier status, Member cost share (e.g., copayment), and of any other reimbursement limitations. If the prescribed drug is subject to reimbursement limitations (e.g., step edit, prior authorization), the pharmacist or Member have three options:

1. the Member may pay cash for the prescribed drug as written, outside of the Health Plan pharmacy benefit;
2. the Member may ask the pharmacist to contact the physician to change the prescription to lower cost drug (e.g., Tier 1 generic), or the pharmacist may recommend that the Member contact the physician; and
3. the Member may leave the pharmacy without a prescription.

V. IMPACT OF THE HANMI PRODUCT ON NEXIUM®

46. The proton pump inhibitor (PPI) drug class is highly utilized within Health Plan and PBM pharmacy benefit programs. As illustrated in the Drug Formulary example above, generic lansoprazole, omeprazole, and pantoprazole are often included in Tier 1. PPIs with patent protection (Nexium® and Aciphex®) are generally included on a higher-cost-share Tier or not included on the Formulary, depending upon the decisions of Health Plan and PBM P & T Committees.

47. Health Plans and PBMs enforce physician prescribing, pharmacist dispensing, and patient utilization of covered drug products using a variety of Drug Formulary enforcement

strategies, described above. Mandatory substitution of generic drugs when available remains an important cost control mechanism. Over 80% of covered prescriptions of many Health Plans and PBMs are dispensed as Tier 1 (e.g., generic) drugs. Health Plans with highly controlled Drug Formularies may have 90% or more of outpatient drugs reimbursed as generic drugs. Health Plans and PBMs incentivize the use of generic drugs through lower-cost-share amounts for Members, and through network pharmacy POS adjudication edits (both described above). Physician prescription decisions depend on patient medical condition and cost considerations. Generally, Formulary cost share incentives influence physicians to prescribe and Members to request a generic or preferred Tier 2 drug rather than a higher Formulary cost share Tier drug.

48. Nexium® is a highly utilized proton pump inhibitor (PPI) drug often found in Health Plan and PBM drug formularies as a preferred product, i.e., in Tier 2. It is currently the only esomeprazole PPI on the market. Accordingly, those Members and healthcare professionals who want to use or prescribe an esomeprazole product have only one option, Nexium®. Despite the availability of generic substitutes for other PPIs, the prescription volume of Nexium® remains high. If the Hanmi product were available, and if Health Plans or PBMs included it on Drug Formularies at a lower Tier, due to lower pricing by Hanmi, Hanmi's product would likely negatively influence the use of Nexium® within managed care plans. This is due to the high influence of Health Plans and PBMs on outpatient prescriptions in the US, and their successful enforcement of compliance with Drug Formularies, as I have described above.

49. If the Hanmi product were available and considered a lower-priced generic alternative for Nexium®, the Hanmi product would likely be placed on Tier 1 of Drug Formularies. Consequently, Nexium® would likely be removed from coverage, or placed on non-preferred Tier 3. Placement on non-preferred Tier 3 would likely include step edits or prior

authorization. For example, a step edit would require Members to demonstrate use of the strontium version of esomeprazole (and/or the use of another generic PPI), before Nexium® would be eligible for reimbursement. A prior authorization would require a physician to contact the Health Plan or PBM to request a patient-specific approval to use Nexium®.

50. As described above, approximately 80-95% of prescriptions are dispensed as generics. The combination of Member incentives to use a generic and Drug Formulary enforcement of limitations and restrictions through the pharmacy POS adjudication system makes it highly likely that Nexium® use would significantly decline.

51. Specifically, if the Hanmi product is allowed to enter the U. S. market, at least two Drug Formulary coverage scenarios for PPIs are possible. One scenario is illustrated below for a typical Open Formulary plan and another scenario is illustrated for a typical Closed Formulary plan. Both coverage scenarios would severely impact Nexium® use.

52. In an Open Formulary plan, Hanmi's low-priced "generic" esomeprazole strontium would be preferred in Tier 1 and Nexium® would be transitioned to a non-preferred brand in Tier 3, possibly with limitations or restrictions (such as step edit), as illustrated in the table below:

PPI Coverage in Open Drug Formulary

Formulary Tiers	Drugs Included in Tier and Relative Cost Index	Member Payment
Tier I - Generic	• *esomeprazole strontium* • *lansoprazole* • *omeprazole* • *omeprazole/bicarbonate* • *pantoprazole*	$10.00

Formulary Tiers	Drugs Included in Tier and Relative Cost Index	Member Payment
Tier II - Preferred Brand	• Dexilant®	$25.00
Tier III - Non-Preferred Brand	• Nexium®* • Aciphex®* • Prevacid®* • Prilosec®* • Protonix®* • Zegerid®*	$50.00

*-Signifies generic first-step edit (generic must be used before brand).

53. In a Closed Formulary plan, Hanmi's product would be preferred in Tier 1 with other generic PPIs. Nexium®, like other PPIs with generic equivalents, would be excluded from coverage altogether, as shown in the table below:

PPI Coverage in Closed Drug Formulary

Formulary Tiers	Drugs Included in Tier and Relative Cost Index	Member Payment
Tier I - Generic	• *esomeprazole strontium* • *lansoprazole* • *omeprazole* • *omeprazole/bicarbonate* • *pantoprazole*	$10.00
Tier II - Preferred Brand		$25.00
Tier III - Non-Preferred Brand	• Aciphex®* • Dexilant®*	$50.00

*-Signifies generic first-step edit (generic must be used before brand).

54. The negative impact on Nexium®, if a low-cost esomeprazole product such as the Hanmi product were available, is illustrated below for two cases. In one case, a Member is already taking and satisfied with Nexium®. In the second case, a Member is starting PPI therapy

and may have requested Nexium®.

55. **Patients already on Nexium®.** Nexium® is one of the most highly prescribed drugs on managed care Formularies. To minimize Member disruption, Health Plans and PBMs generally announce coverage changes for highly popular drugs such as Nexium®. After Hanmi's product is introduced and added to the Formulary as a Tier 1 drug by the PBM, Members are normally informed that their cost for Nexium® will increase, but a less expensive alternative with the same active ingredient is available at a lower copayment. Members would be advised that they may call or visit their physician, or ask their pharmacist to contact their physician, to request a change to their prescription.

56. **New Patients Who Request Nexium®.** Members often request specific drugs in response to an advertisement, Internet information, or advice of a friend or relative who have had a positive experience with that drug. If a PPI is medically appropriate and Nexium® is requested by the Member, the physician may explain that Nexium® may be available at a higher cost (or may be excluded from coverage), but a drug with the same active ingredient (esomeprazole) is available at a lower cost. The physician may also discuss other low cost non-esomeprazole PPI options. However, if the Member desires the same active ingredient as Nexium® and does not want to pay the higher price, the physician would prescribe Hanmi's esomeprazole strontium delayed-release capsules because that would be the only other esomeprazole drug available.

57. Based upon the above scenarios, if Members starting PPI therapy are not provided an opportunity to try Nexium®, and after Members are converted away from Nexium® to the Hanmi product, the use of Nexium® will decline and are not likely to return to current levels. If, for whatever reason, Members are dissatisfied after being started on or being converted to the

Hanmi product, or if the Hanmi product is later removed from the market by a court decision, it is highly unlikely that these Members would return to Nexium®.

58. If the Hanmi product is the first esomeprazole drug that the Member has tried and the Member has become dissatisfied with its effect, or if the Hanmi product is removed from the market, the physician would likely recommend that the Member try a drug with a different active ingredient such as one of three other low cost, Tier 1 generic PPI drugs (lansoprazole, omeprazole, or pantoprozole), before recommending a preferred brand product. Only after these options prove unsatisfactory would a physician recommend a higher cost brand PPI option. Even in this case, the physician may recommend other brand PPIs without generic equivalents, such as Aciphex®.

59. If a Member had previously switched from Nexium® to the Hanmi product and desired for some reason to switch back, the Member would still face significant barriers. Once Nexium® has been transitioned to a higher Tier as a result of the introduction of Hanmi's lower-cost drug, the Member would be required to pay a much higher copayment to switch to Nexium®. Or, if Nexium® has been excluded from coverage altogether, the Member would have to pay the entire cost of the product. In addition, Nexium® may be subject to a prior authorization or step edit requirement. Thus, for many Members, switching back to Nexium® is unlikely, and the use of Nexium® is not likely to recover to its previous levels.

VI. INTRODUCTION OF THE HANMI PRODUCT TO THE MARKET IS LIKELY TO CAUSE CONFUSION

60. The name "Esomeprazole Strontium delayed-release capsules" used in connection with the Hanmi product may be confusing to Members, pharmacists, physicians, or even managed care pharmacists. The use of Tier 1 drugs is encouraged and incentivized through use

of a lower Member cost share. Even though the Hanmi product is not directly substitutable (because it contains a different salt than Nexium®), physicians, prescribing nurse practitioners, pharmacists, and other health care professionals are likely to consider the Hanmi product to be a therapeutic alternative to Nexium® because both contain esomeprazole as the active ingredient. This fact is clearly evident from the product label and associated literature. Prescribers and pharmacists are aware that different salts exist for many drugs with the identical active ingredient. Therefore, these health care professionals may conclude that the particular salt form has no impact on the therapeutic use of the drug.

61. The potential confusion is made more likely because the prescribing information of the Hanmi product is almost identical to that of Nexium®. Exhibits B and C to this declaration are the Hanmi product label[4] and the Nexium® label[5], respectively. Many of the statements and claims made in the label of the Hanmi product (esomeprazole strontium) refer to, or rely upon, the Nexium® (esomeprazole magnesium) data and prescribing information. Both the Hanmi product and Nexium® have virtually identical labeled indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions and drug interactions. This similarity provides further market and prescriber confusion, and is likely to contribute to the belief that the Hanmi product is a therapeutic alternative to Nexium®.

62. Marketing by Hanmi is also likely to confuse Members who may request prescriptions for the Hanmi product because they may believe it has been approved by the FDA as a generic substitute for Nexium®. In fact a press release that the esomeprazole strontium

[4] Esomeprazole strontium prescribing information. Hanmi Pharm. Co. Ltd., Seoul, Korea.

delayed-release capsule version is an "....improved version of Nexium® of AstraZeneca..." (See Exh. D).[6] Members may be exposed to this material and be prompted to request physicians to prescribe the Hanmi esomeprazole strontium delayed-release capsule version. Members often request and receive specific drugs from their physicians in response to marketing and advertisements or other public information. Member-initiated conversions to the Hanmi product, based upon the belief that the Hanmi product is equivalent to or better than Nexium®, are therefore likely to further erode Nexium® use.

63. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this Declaration was executed this 19th day of August 2013, at Washington, District of Columbia.

ROBERT P. NAVARRO, PHARM D.

[5] Nexium® (esomeprazole magnesium) delayed-release capsules. Astra Zeneca Pharmaceuticals LP, Wilmington, DE. (Exh. B)

[6] "U.S. FDA OKs sale of S. Korean's improved version of Nexium®", Globalpost Web Site, available at http://www.globalpost.com/dispatch/news/yonhap-news-agency/130807/us-fda-oks-sale-s-koreas-improved-version-Nexium®